



**American  
Red Cross**

**National Headquarters**  
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**FOOD AND DRUG ADMINISTRATION  
TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY  
ADVISORY COMMITTEE**

**IMPLEMENTATION OF NEW DONOR DEFERRAL CRITERIA  
TO RESPOND TO THE THREAT OF vCJD**

**October 25, 2001**

**STATEMENT OF THE AMERICAN RED CROSS**

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Mr. Chairman and Members of the Advisory Committee:

The American Red Cross is committed to developing a stable and sustained blood supply to meet increasing patient needs and hospital demand for these life-saving products. In June, we briefed this committee on our plans to make chronic cyclical shortages a thing of the past. We shared with you the new systems we were implementing to monitor the amount of blood collected, distributed and in inventory at our blood centers nationwide, as well as our market research and outreach programs to reach generous blood donors.

Even prior to the attacks on our country, the summer campaign highlighted our ability to increase blood collections by using the right strategy and resources. Our goal is now to make this effort sustainable. By expanding and refining strategies we are working to ensure our collections goal of 9 million units by FY '06.

Responding to the Needs of New York

The Red Cross is committed to meeting the needs of patients throughout this country. In June, the committee heard from New York City hospitals, the New York Blood Center, and New York Health Commissioner Novella about concerns related to the potential impact of expanded donor deferral criteria for vCJD. It was estimated by New York Blood Center that the deferral would result in the cancellation of over 7,000 transfusions each month in New York-New Jersey hospitals in the metropolitan area. In August, the Red Cross responded to this need by announcing plans to provide blood to the New York City area to avert any supply crisis during a transition away from that area's dependence on European blood.

In August, in response to these concerns, the American Red Cross committed to provide 180,000 units of blood in order to cover the loss of blood imported from Europe by the New York Blood Center as well as potential losses of donors in the New York City area. We communicated this pledge of assistance to the FDA, New York Blood Center, the New York State Public Health Commissioner, the Greater New York Hospital Association, and to the New York congressional delegation. Since that time the New York Blood Center has indicated that they, in fact, will not

***We'll be there.***

need additional units of blood pledged by the American Red Cross to overcome the elimination of their "Euroblood" program.

The Red Cross was also able to immediately mobilize its unique national network to respond to the horrific attacks in New York City and Washington, D.C. The Red Cross moved more than 5,000 blood donations to the two Red Cross blood centers closest to these metropolitan areas. Unfortunately, only about 1,000 donations were actually needed New York City and New Jersey hospitals.

#### Anticipated Impact of vCJD Donor Deferral

The committee has asked us to discuss the anticipated impact of an expanded donor deferral for vCJD. The policy implemented on October 15<sup>th</sup> by the Red Cross will defer:

- Donors who have spent time in the United Kingdom for a cumulative total of three months or more since 1980 **or**
- Donors who have spent time in any other European country for six months or more since 1980 **or**
- Donors who have received a blood transfusion in the United Kingdom.

We had originally planned to implement an expanded vCJD deferral policy on September 15, 2001. In light of the tragic events of September 11<sup>th</sup>, the unknown need for blood immediately following the attack, and postponement of training for our staff, we decided to implement the deferral policy on October 15, 2001.

In May to prepare for the expanded deferral, the Red Cross commissioned Wirthlin Worldwide to perform a telephone survey of a nationally representative sample of Red Cross donors to determine the number of individuals that would be deferred under the new policy. The findings of this survey indicate a total of 3% (+ or - 0.6%) of eligible donors will be deferred and additional 1% will erroneously self-defer, even though they are actually eligible to donate. Taken together, the results of the survey indicate that about 4% of our donors, or approximately 235,000 units may be lost to this expanded deferral. Since October 15<sup>th</sup> we have been monitoring deferral rates on a daily basis to determine the impact of collections and inform decisions on collection goals. It appears that through our efforts to educate our current donors (5 million) and sponsors, the on-site deferral rates will be substantially lower than 4%.

#### Increased Collections

Prior to September 11<sup>th</sup>, the Red Cross had already seen a dramatic increase in collections resulting from our initiatives to grow collections and mitigate losses anticipated from the expanded vCJD deferral. Presenting donors to the Red Cross surged to 7.5 million in FY 2001, a 6.1% increase compared to FY 2000. This corresponds to an 8.5% gross increase in productive units when one uses FY 2000 deferral rates that do not include our losses due to finger sampling or about 543,000 more units of blood in FY 2001. Our collections in July and August this year have increased by 8% over these same months last year. These increased collections had a direct impact on our inventory. Our total red blood cell inventory was 33% higher this August than last year and Type O inventory increased by 83% over last August.

There has been a tremendous outpouring of Americans wishing to give blood in response to the attack on our country. In this period of uncertainty, the American Red Cross has a responsibility to be prepared for any contingency such as another terrorist attack on American soil and the potential need for blood resulting from U.S. military action. During the immediate aftermath of the September 11<sup>th</sup> attacks, we expanded blood collection, storage, and freezing capacity so that we didn't turn generous blood donors away. We are now continuing those activities so that we

can build and maintain a large, readily deployable liquid inventory of blood and grow our frozen supply.

The two to three day inventory of blood that has traditionally been tolerated in this country is inherently inadequate. At present the Red Cross has a 10 day inventory – our goal is to maintain a sustainable 7-10 day readily deployable liquid inventory in addition to our frozen blood reserve. We continue to move forward with our long-term initiatives to build a stable and sustained blood supply. We have been forecasting collections for over a year and we continue to refine our projection and demand models.

#### Conclusion

On behalf of the Red Cross, thank you for the opportunity to provide our views and strategies to increase blood collections. We are confident and optimistic that the goals of safety and availability can be achieved through dedicated resources and coherent strategies that we have been implementing throughout the Red Cross national system.